An Assessment of the United States Measurement System:

Addressing Measurement Barriers to Accelerate Innovation

Appendix A

Descriptions of NIST USMS Workshops

NIST Special Publication 1048

NIST
National Institute of Standards and Technology
Technology Administration, U.S. Department of Commerce

Description of NIST USMS Workshops

Introduction

The purpose of NIST-Sponsored USMS Workshops is to engage industry and other government agencies in the assessment of measurement barriers to technological innovation. This USMS mechanism engages stakeholders in the USMS to collaboratively identify measurement problems that impede innovation, potential solutions to them, potential solution providers, as well as direct stakeholder input to the comprehensive USMS assessment process. Workshop participants have documented these measurement problems in the form of case studies using the USMS-established format. These are compiled in Appendix B of this report.

Fifteen NIST – USMS workshops were held as of June 1, 2006 with an additional three scheduled for later in 2006. Workshops have been:

- Organized as stand-alone events or as an add-on to existing technical conferences and workshops; (Stand-alone workshops were open to the public and announced publicly);
- Focused on measurement problems impeding technological innovation in the relevant technical area;
- Representative of broad stakeholder participation (industry, government, academia, standards developers, professional organizations) within the relevant technical area targeted; and
- Opened with a USMS overview, to provide a framework for the discussion

The following workshops were conducted as of June 1, 2006. Abstracts for these workshops are presented in this document.

The following are upcoming workshops.

Workshops Conducted as of June 1, 2006

Optical Radiation Measurements

May 9, 2006

Date: May 9, 2006

Venue: NIST, in conjunction with the annual meeting of the Council on Optical Radiation Measurements

Abstract: Across the innovation spectrum, from laboratory to marketplace, measurements are a necessary means to important ends. Businesses, universities, and government laboratories need access to ever-improving measurement capabilities if the United States is to remain a technology leader and reap the resulting economic benefits. But will these essential tools be available when they are needed?

The National Institute of Standards and Technology (NIST) has launched an ambitious assessment of the nation's decentralized measurement system, one that is far more encompassing than the few studies done over the last several decades. The aim is to determine whether this vital infrastructure-the United States Measurement System or USMS-can effectively address multiplying needs for ever-more exacting and reliable measurement tools and associated services, such as accredited calibration and testing laboratories.

Because of the large and decentralized organization of the system, this first-ever survey of measurement needs and assessment of the health of the USMS must be carried out collaboratively. Workshops and conferences devoted to defining and prioritizing measurement needs are being conducted on an ongoing basis to:

- Identify current and future measurement infrastructure needs
- Identify systemic gaps and weaknesses in the USMS itself
- Engage stakeholders in the USMS to collaboratively seek solutions

The USMS workshop will provide direct stakeholder input to the comprehensive USMS assessment process. The USMS assessment will be the foundation for the USMS roadmap and provide a resource for strategic planning and budgeting exercises conducted by all USMS contributors, including NIST.

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Credentialing Program for Security Assessment Service Providers

Date: April 26, 2006

Venue: NIST

Abstract: Title III of the E-Government Act (Public Law 107-347), entitled the Federal Information Security Management Act (FISMA) of 2002, requires each federal agency to conduct periodic testing and evaluation of the effectiveness of its information security policies, procedures, practices, and security controls to be performed with a frequency depending on risk, but no less than annually. In addition to the FISMA requirement, the Office of Management and Budget (OMB) Circular A-130 requires every federal information system to be certified and accredited every three years or when significant changes occur within the system. The security certification process which supports security accreditation, requires the

comprehensive assessment of the management, operational, and technical security controls within the information system to determine the overall effectiveness of the controls (i.e., are the controls implemented correctly, operating as intended and producing the desired outcome with respect to meeting the security requirements for the system). The results from these security control assessments provide authorizing officials with critical information and evidence needed to make credible, risk-based decisions on whether to place an information system into operation or continue its operation.

To assist federal agencies in implementing FISMA, NIST established the FISMA Implementation Project. Phase I of the FISMA Implementation Project focused on the development of a suite of security standards and guidelines required by the FISMA legislation as well as other FISMA-related publications necessary to create a robust information security program and effectively manage risk to agency operations and agency assets. Phase II of the project is focusing on the development of a credentialing process for public and private sector organizations that provide security certification services for federal agencies.

In order to achieve credentialed status, information security service providers will have had to demonstrate capability and competence in the application of the NIST security standards and guidelines associated with the security certification process. Developing a network of credentialed organizations with demonstrated capability and competence in conducting security assessments will give federal agencies greater confidence in the acquisition and use of such services and lead to increased information security for the federal government.

The workshop topics will include:

- Overview of the FISMA Implementation Project;
- Overview of Key Documents Produced in Phase I of the Project;
- Strategy and Vision for Phase II of the Project;
- Prospective Models for Credentialing of Security Assessment Organizations; and
- Proposed Requirements for Service Providers and Oversight Bodies.

Concurrent breakout sessions will be held for prospective credentialing organizations/authorities, service providers, and consumers of security assessment services to discuss workshop topics.

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Measurement Challenges in Proteomics

Date: March 12, 2006

Venue: Sheraton Boston Hotel, The workshop is being held in conjunction with the US HUPO 2006 Annual Meeting (http://www.ushupo.org)

Workshop Goals: Survey (identify and prioritize) measurement needs that addresses the technical infrastructure and hurdles (measurement science, standards, and data) in the field of proteomics.

Identify how best to transfer knowledge and share priorities across organizations in order to build strong collaborations and partnerships.

About the Workshop: The word “proteome” is derived from PROTEins expressed by a genOME, and it refers to all the proteins produced by an organism, much like the genome is the entire set of genes. The human body contains a vast number of different proteins, each having different functions. As the main components of the physiological pathways of the cells, proteins serve vital functions in the body. Pro-

teomics plays an important role in drug discovery, diagnostics and molecular medicine, providing a link between genes, proteins, metabolites, and disease.

The National Institute of Standards and Technology (NIST) is facilitating a U.S. Measurement System (USMS) initiative that will be undertaken in close cooperation with the private and public sectors to ensure that the nation's highest-priority measurement needs are identified and met in the 21st century. NIST plans to publish a USMS Roadmap on a regular basis, reporting to USMS customers and stakeholders on what should be done, by NIST and others, to meet the needs of the USMS, and delineating the consequences of not meeting those needs. The Measurement Challenges in Proteomics Workshop is part of this initiative and will endeavor to survey (identify and prioritize) system-wide needs in coordinating, performing and using protein measurements.

The inability to establish performance criteria to better understand the quality of proteomic technique results, has led to poor confidence in protein measurement techniques, difficulty in assessing the agreement of different experiments, conflicting reports in the literature, and lost opportunities. If proteomics technologies are to successfully make their way into clinical diagnostics, universally accepted metrics will be needed at many steps along the way to help clarify experimental results and protocols and make them comparable.

By participating in this workshop, members will help identify and prioritize a measurement needs agenda that addresses the technical infrastructure (measurement science, standards, and data) in the field of proteomics. Participants will also identify how best to transfer knowledge and share priorities across industry, government, funding agencies, regulatory agencies, educational and not-for-profit institutions in order to build strong collaborations and partnerships. By the end of the workshop, a roadmap of the measurement needs should be outlined. The steps needed to address these needs as well as the consequences of inaction will be stated.

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Large-Area, Flexible Electronics and Photonics

Date: March 6-7, 2006

Venue: NIST Advanced Measurement Laboratory, Gaithersburg, MD

Abstract:

The United States Measurement System

NIST is leading an effort to document future needs for the United States Measurement System (USMS), the complex of all methods, instruments, entities, institutions, and standards involved in measurements of products and processes of significance to the economy, security, and quality of life. Now more than ever, there is a need to create a comprehensive mechanism to anticipate needed measurement infrastructure and to make informed strategic choices to achieve the greatest impact.

Large-Area, Flexible Electronics and Photonics

A technology area poised for significant growth is flexible, large-area electronics and photonics. An exciting array of new devices and applications are now possible with materials amenable to incorporation on flexible substrates, via low cost, high volume manufacturing. However, the systematic development of flexible, large area electronics is difficult because of the enormous range of potential materials and manufacturing methods. The concurrent development of multiple material platforms and processes, the demand for new diagnostic probes, tools, and methods and a lack of standardization may be limiting progress.

Objective

This workshop seeks to bring together stakeholders from industry, government, and academia to assess the measurement and standards infrastructure available to address technological challenges in flexible, large-area electronics and photonics and to identify significant gaps that must be closed. These needs may include new diagnostic probes, tools, and measurement protocols for an extensive array of potential materials, applications, and manufacturing methods. Discussions from the workshop will be compiled into a report that will be used to inform future investments in USMS infrastructure needed to support the development of this technology.

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Improved Antibody-Based Metrology in Flow Cytometry

Date: February 23, 2006

Venue: NIST, Building 101, Lecture Room A

Abstract: This U.S. Measurement System (USMS) workshop is one of a series to assess the nation's needs in the area of standards and technologies for immunoassay-based measurements. Flow cytometry (FC) is an important tool in clinical medicine and cancer and immunology research. The objective of this USMS workshop is to assess barriers to technological innovation in quantitative cytometer measurements in the United States At present, cytometers are used in clinical laboratories to estimate the relative number of specific receptors expressed on the surface of lymphocytes from the blood, lymphnodes, bone marrow, and other body fluids. The number and type of receptors are indicators of the lineage, clonality, stage of differentiation, and state of activation. Technological advances are needed to realize quantitative FC measurements to provide more accurate measurements of the absolute number of specific receptors expressed on the surface of cells. Quantitative measurements are also critical for multiple fluorescence channel, multiplexed bead, and imaging cytometers. The USMS workshop aims to bring together leaders in cytometry-based medical diagnostics, diagnostic testing, clinical laboratory medicine, and regulatory affairs to identify the fundamental and common metrology barriers to advances in flow cytometry. In addition, the workshop(s) will aim to foster partnerships and collaborations for development of the infrastructural metrology needed to insure scientifically sound measurements.

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Developing New Standards for Autoantibody Measurement; Bringing Metrology to Serology

Date: February 21-22, 2006

Venue: NIST

Abstract: This USMS workshop is the first in a series to assess the nation's needs in the area of standards and technologies for immunoassay-based measurements. In vitro diagnostic tests based upon antigen/antibody interactions are used extensively as aids in the diagnosis of cancer and most other diseases,

including; autoimmune, cardiovascular, endocrine, gastrointestinal, infectious, metabolic, neurological and renal disorders. Two of the largest health problems in the country are autoimmune disease and cancer, which combined, affect almost half of all Americans. The determination of circulating autoantibodies has long been a part of clinical medicine in autoimmune disease and there are many FDA approved autoantibody tests currently marketed. Autoantibodies are fast becoming an important diagnostic tool in cancer as well, with millions of dollars in NIH funding directed toward autoantibody discovery for early diagnosis and prevention of cancer. The central technical feature shared by all autoantibody diagnostic assays is the capture of autoantibodies from serum using immobilized autoantigen. However, there is enormous variability in these tests that has led to confusion over results, variable degrees of confidence in their utility and even misdiagnosis of patients' disease. Part of the problem is that there are currently no autoantigen standard reference materials or protocols. In addition, there is little coordination between diagnostic developers, clinicians, and regulators regarding standards and best practices.

The USMS workshop aims to bring together leaders in autoantibody-based medical diagnostics, diagnostic testing, clinical laboratory medicine, and regulatory affairs to identify the fundamental and common metrology issues that underpin most antibody-based serodiagnostics. In addition, the workshop(s) will aim to foster partnerships and col

laborations for development of the infrastructural metrology needed to insure scientifically sound autoantibody-based diagnostics.

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Standards and Measurements for Assessing Bone Health

Date: February 4, 2006

Venue: 12th Annual Meeting of the International Society for Clinical Densitometry

Sheraton San Diego Hotel, San Diego, CA

Abstract: Each year in the United States, over 1.5 million bone fractures due to osteoporosis occur. Treatment costs exceed $14B per year. These numbers are expected to double or triple in the next 40 years as the average age of the US population increases. Bone mineral density is a common metric for assessing bone health and the risk of fracture. However, the current practice of using dual X-ray absorptiometry (DXA) measurements and images to determine bone mineral density does not provide an adequate level of confidence in the predictive outcome. Standardization of DXA scan measurements, calibration of the DXA scan equipment, edge detection, and validation of imaging software are a few of the many challenges facing health care providers today. The technologies used currently by health care providers to determine bone strength and viability do not capture all the parameters that are required to predict fracture risk accurately. Understanding how other parameters such as structure and microarchitecture will be useful in assessing bone health. Developing new methods to measure those parameters will be critical to achieve greater predictive accuracy for risk due to bone fracture from osteoporosis and will contribute to lowering health care costs.

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Biophotonic Tools for Cell and Tissue Diagnostics

Date: January 22, 2006, 6:00 p.m. - 8:30 p.m.
Venue: San Jose, California, USA

Through this workshop, we will identify the critical measurement needs for biophotonic tools used in tissue and cell diagnostics. A statement of these needs will become part of the biophotonics segment of a national assessment of the U.S. Measurement System infrastructure. This roadmap will enable proactive development of measurement infrastructure to enhance the manufacturing efficiency and quality, improve interoperability, and accelerate the acceptance of biophotonics-related instruments and technologies.

In order to maintain the current rapid advance of biophotonics in the United States and to enhance our competitiveness worldwide, key measurement tools must be in place. The right measurement capabilities will improve both manufacturing efficiency and quality, and promote acceptance of biophotonics-based instruments and technologies through improved interoperability. This workshop is a part of a wide-reaching effort by the National Institute of Standards and Technology to improve the U.S. technology base.

It will focus on diagnostic techniques involving the interaction between biological systems and photons. Through invited presentations by industry representatives and panel discussion, the near- and far-term measurement needs will be evaluated. As a result of this workshop, a road-mapping document will be prepared on the measurement tools needed for biophotonic cell and tissue diagnostics. This will become a part of the larger road-mapping effort to be presented to the nation as an assessment of the U.S. Measurement System. The information will be used to highlight measurement needs to the community and to facilitate solutions among key stakeholders in industry, government, and academia.

Measurement and Standards Needs in NanoBiotechnology

Date: January 19, 2006

Venue: Jesse Jones Graduate School of Management, McNair Hall in the Shell Auditorium

Rice University - Houston, Texas

Abstract: This workshop will identify the most critical measurement and standards needs in this important new area of the USMS presently being assessed by NIST.

The workshop topics will include the following:

A. Medical/Clinical/Pharmaceutical (drug delivery, targeted therapeutic agents, nanomaterials devices drug discovery)
B. Medical Imaging (nanobased contrast agents, other imaging modalities)
C. Manufacturing (nanoparticles handling, manufacturing, safety, scale-up)
D. Basic science (structure & dynamics of biomolecules, sensing at the single molecule level)
E. Physical Characterization (dimension, composition, purity, surface chemistry, instrumentation)

Metrology Challenges for Broadband Communications

Date: Fall 2005 - Spring 2006

Venue: Multiple sessions/venues - see below for updated list of confirmed sessions

Abstract: Broadband communications continues to be a significant and growing market in the United States and global economies, as well as a critical enabling technology for a wide range of applications and industries. This multi-session, multi-venue workshop, being developed by NIST in partnership with engaged communications-industry stakeholders as part of the NIST U.S. Measurement System (USMS) initiative, seeks to identify critical measurement issues relating to the innovation infrastructure required for universal, ubiquitous, and seamless broadband access.

Intended output from these workshop sessions includes:

- Determination of what measurements, or entire classes of measurements, need to be developed or improved to enable anticipated technical innovations.
- Strategies for appropriate and efficient metrology support that could be provided or developed by noncommercial research labs (NIST or other government-funded labs, as well as academic labs).
- Examination of R&D and measurement-standards-development processes and priorities in the United States compared to other countries/regions.

Stakeholders include manufacturers, suppliers, providers, and users of communications equipment, products, and services, as well as related trade and standards organizations. The scope of workshop sessions, intended to be co-located with major conferences and meetings of appropriate industry segments, will span various technologies/platforms (wireless, wired, optical, satellite, etc.), services (voice, video, data), protocols, network layers (physical, access, routing/switching, transport, etc.), and applications (interpersonal, public safety, distributed computing, information exchange, entertainment).

NIST is actively soliciting input on potential co-location venues, suggested panelists/speakers, and session content. For comments or suggestions on any of these areas, or for more information, contact any of the following NIST staff.

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Imaging Metrology for Telemedicine Workshop

Date: Part II: December 7, 2005, 8:30 a.m. - 5:00 p.m.
Venue: NIST, Gaithersburg, MD

Abstract: Critical diagnostic and clinical standards and techniques are required for the evaluation of medical images, medical imaging devices (includes both image acquisition devices such as digital cameras and microscopes, and display devices such as CRTs and LCDs), the evaluation of computer assisted diagnostic (CAD) tools, and the effects of compression on image quality. These evaluation processes are increasingly critical as new medical diagnostic and imaging techniques become available and as new or

improved display technologies come into use. There is also a growing need to communicate and render image information across different information display systems. Diagnosticians in many areas have integrated new imaging devices into their practice, often without regard to fidelity issues that to too many are not particularly obvious. Thus, it has become routine, for example, for many doctors to take images home with them for viewing in the comfort of their homes. Images are routinely emailed to consulting physicians without regard to whether the displays on which they are viewed meet minimum performance standards. Images may be compressed for storage or for transportation across wireless systems. Improved rendering of transmitted medical images will lead to lower cost healthcare services; especially for remote, sparsely populated regions of the United States.

The workshop will explore the challenge and demands upon the US measurement system (USMS) by the new technologies and critical applications in medical imaging and telemedicine, and address how the USMS should be redefined to meet its role.

Four areas that are crucial to establishing effective diagnostic evaluation and imaging in which the USMS can take a significant role, will be the addressed by this and subsequent workshops.

- evaluation of medical images
- medical imaging devices
- evaluation of computer assisted diagnostics
- storage and forwarding of medical images

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Metrology for the Magnetic Data Storage Industry

Date: October 20-21, 2005
Venue: NIST, Boulder

Abstract: The data storage industry is rapidly moving into metrology realms far below present measurement capabilities. As the areal density is pushed to 100 Gbit/in^2 and beyond, with bit dimensions of a few nanometers, nanoscale measurements become a priority. New technologies being considered for commercial storage media include self-organized magnetic arrays, patterned films, heat assisted structures, perpendicular anisotropy media, and exchange-coupled layers. New device geometries and operation paradigms required for read heads and magnetic random access memory (MRAM) will also play a key role in future developments. Not only is scale important in these innovative devices, but also the recording industry must now deal with nanoscale effects at the picosecond time scales and thermal changes of hundreds of degrees kelvin.

Generally available metrology solutions have not kept pace with the need, forcing industry and academia to step in with either custom metrology or trial and error technology development.

Metrology is needed to fabricate magnetic structures with 1-10 nm dimensions, to measure their chemical properties and structure, to measure the magnetization vector of each atom and nanoparticle in these structures and their interactions, to image magnetic domain structures with 1 nm resolution, to probe magnetic interactions in buried layers, and to develop modeling methods for handling multi-size scales ranging from 1 nm to 1 m. In addition, these measurements need to be done in actual operating environments and at picosecond time scales. Magnetization reversal by domain processes or spin rotation methods should be observable and thereby enable engineering of devices for high speed switching and sensing. Targeted development of the underlying metrology and instrumentation needed to make reliable repro-

ducible measurements of device performance and materials' properties should enable the successful incorporation of next generation devices into commercial data storage products.

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Metrology Needs for Micro/Nano System Technologies

Date: September 22, 2005

Venue: METRIC (MEMS Industry Group Workshop) - Pittsburgh, PA(www.memsindustrygroup.org/METRIC2005/NIST_Metrology.asp)

Abstract: Micro/Nano Technologies (MNT) including MicroElectroMechanical Systems (MEMS), MicroOptoElectroMechanical Systems (MOEMS), and Microfluidic Systems may arguably be viewed as the next-generation technologies capable of enabling unique and unprecedented capability and performance as sensors and actuators. Consequently, these new machines and devices are finding application in an array of economic sectors, including automotive, aerospace, telecommunication, healthcare and biotechnology. Some of the current products that are based on these technologies include accelerometers for airbag deployment, digital light processors for high definition video projection and inkjet heads for inkjet printers. Emerging products include DNA analysis tools and portable diagnostic systems for bedside care, light modulators for telecommunications, robotic sensors and manipulators, microscopy tools and chip scale atomic clocks.

Developers of these technologies still struggle in fabricating highly accurate and reliable products because of a lack of adequate metrology. Some of these issues include the need for improvements in static and dynamic performance testing, and the development of reliability and compatibility test methods for the thin-film materials. The need for international standards is also prevalent and the United States must take a leadership role in order to ensure that the US can be competitive on the world market.
Definition of US Measurement System needs for Micro/Nano Technologies will start with drawing on results of previous workshops followed by networking with partners in industry, industry groups, universities, and other government labs to develop a draft report. The draft report will be delivered in advance of the USMS workshop to the participants and others.

The feedback on the report will be collected at the workshop and by email correspondence, and in ongoing workshops (e.g. microTAS, Nov 2005) to form the first "living" report on MNT metrology needs. This report will be delivered to the NIST USMS committee. An additional outcome of this effort that is in discussion will be the development of an MNT metrology roadmap that will be used by our industry partners.

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Imaging Metrology in Telemedicine

Venue: Part 1: American Telemedicine Association 2005 Fall Forum, Palm Springs, CA
http://www.americantelemed.org/news/newres.htm (Day 3 program)
Part 1: September 13, 200

Venue: Part 2: NIST, Gaithersburg, MD
Part 2: December 7, 2005 (8:30 a.m. - 5:00 p.m.)

Abstract: Critical diagnostic and clinical standards and techniques are required for the evaluation of medical images, medical imaging devices (includes both image acquisition devices such as digital cameras and microscopes, and display devices such as CRTs and LCDs), the evaluation of computer assisted diagnostic (CAD) tools, and the effects of compression on image quality. These evaluation processes are increasingly critical as new medical diagnostic and imaging techniques become available and as new or improved display technologies come into use. There is also a growing need to communicate and render image information across different information display systems. Diagnosticians in many areas have integrated new imaging devices into their practice, often without regard to fidelity issues that to too many are not particularly obvious. Thus, it has become routine, for example, for many doctors to take images home with them for viewing in the comfort of their homes. Images are routinely emailed to consulting physicians without regard to whether the displays on which they are viewed meet minimum performance standards. Images may be compressed for storage or for transportation across wireless systems. Improved rendering of transmitted medical images will lead to lower cost healthcare services; especially for remote, sparsely populated regions of the United States

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Four areas that are crucial to establishing effective diagnostic evaluation and imaging in which the USMS can take a significant role, will be the addressed by this and subsequent workshops.

A. evaluation of medical images
B. medical imaging devices
C. evaluation of computer assisted diagnostics
D. storage and forwarding of medical images

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NanoBiotechnology

Date: August 28-September 1, 2005 and others

Venue: Series of Events, starting with American Chemical Society Washington DC National Meeting & Exposition and others

Abstract: NanoBiotechnology is the study and manipulation of biological molecules, cellular components and engineered materials with nanometer-scale dimensions. Nanoscale materials with unique properties have application in drug delivery, therapeutics, imaging and diagnostics. In addition, nanoscale analytical tools and techniques are improving our ability to understand and manipulate living cells and biological molecules, potentially leading the way to new sensors, materials, electronics, and manufacturing processes. These advances are occurring through the multidisciplinary integration of nanotechnology with biology and medicine.

The development of nanobiotechnology is limited by the ability to manufacture, chemically modify, manipulate, purify, quantify and characterize nanoparticles. In addition, the fate of nanoparticles in the body and in the ecosystem is largely unknown. This workshop will aim to identify the most critical measurement and standards needs in this developing area of nanobiotechnology. Direction for these efforts will be sought from industrial partners, US government agencies and academic institutions that work in close alliance with companies and/or medical centers.

The USMS NanoBiotechnology Workshop will bring together representatives from industry, government, and academic laboratories to identify industrial metrology needs. Based on input from our stakeholders, we will develop a long-term vision for research and for NanoBiotechnology. The workshop will seek to identify the best courses of action and the organizations that can carry out the work. This will be one small step for metrology that helps NIST and its partners define critical industry needs in the short and long-term.

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Upcoming Workshops

Imaging as a Biomarker: Standards for Change Measurements in Therapy

Date: 14-15 September 2006,

Venue: NIST, Gaithersburg, Maryland

Imaging as a biomarker of drug response is becoming an increasingly important field of research. The Food and Drug Administration (FDA), the National Cancer Institute (NCI), and the Centers for Medicare and Medicaid Services (CMS) have agreed to collaborate on improving the development of cancer therapies and outcomes for cancer patients through biomarker development and evaluation <http://www.fda.gov/oc/mous/domestic/FDA-NCI-CMS.html>. A similar effort across the National Institutes of Health's (NIH's) Institutes and Centers (ICs) is being planned. Biomarkers are biological indicators of disease or therapeutic effects that can be measured by in vivo biomedical imaging and molecular imaging in particular, as well as other in vitro or laboratory methods. Recent work has shown that biomedical imaging can provide an early indication of drug response by use of X-ray, CT or PET-CT.

Many sources of uncertainty exist in imaging as a biomarker. Biological variability, for example, is a factor both drug- and patient-dependent and thus difficult to characterize or model. However, other uncertainties are associated with the image data collection platform and the robustness of software tools required for reliable, quantitative measurement of change over time, such as tumor volume, radioactive tracer activity, or contrast agent dynamics. All these sources of uncertainty significantly affect the statistical power of clinical drug or therapy trials.

The development of standards for image quality control, image data collection, and benchmarking of change analysis software tools, as well as image-specific statistical methods, could significantly reduce the size of clinical trials for drug response. The costs of a drug submission to the FDA by the pharmaceutical industry may soon exceed $1 billion. The use of standardized imaging methods may reduce these trial costs.

The scope of this workshop is focused on the need to standardize imaging methods for data collection and data analysis in the context of drug or radiation therapy trials. Suggested topics for discussion are:

- Instrument quality control over the time sequence of a trial
- Harmonization of data collection across different commercial imaging platforms
- Creation of standardized, objective performance metrics for image-analysis software using reference image databases or test beds
- Standardized statistical methods for change measurement
- Archival and access methods for image storage, related meta-data, and clinical outcome data
- Innovative methodologies for the integration of image and other data for clinical decision making

Workshop participants should address the following questions with respect to the above topics:

- What technological innovations are at stake?
- What is the economic significance of the innovations?
- What technical barriers to the innovations impede progress to the marketplace?
- At what stages of innovation (R&D, Production, Marketplace, End Use) do the technical barriers appear?
- What parts of the technical barriers are measurement science or standards development?
- What are the potential solutions to the measurement and standards development problems?
- Who are potential providers of solutions?
- Are there critical roles for agencies of the federal government?

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Medical Devices Metrology and Standard Needs

Date: November 14 - 17, 2006

Venue: Meeting in Conjunction with ASTM F04 Committee Meeting, Atlanta, GA

Abstract: Not available at the time of this printing.

Service Life Performance of Advanced Polymeric Materials and Composites; Workshop 2

Date: December 4, 2006

Abstract: Not available at the time of this printing.